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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/614,631	07/12/2000	John Dennis Hilgren	163.1382US01	2124

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EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/614,631

Applicant(s)
Hilgren et al.

Examiner
John Pak

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1616



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 16, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above, claim(s) 10-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 31-34 is/are rejected.
- 7) ☒ Claim(s) 4 and 32-34 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 1-34 are pending in this application.

Claims 10-30 stand withdrawn from further consideration as being directed to non-elected subject matter. Claims 1-9 and 31-34 will presently be examined.

Claims 4 and 32-34 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. .

(1) Claims 4 and 32 depend on claims 3 and 31, respectively. Claims 4 and 32 recite 33 ppm peroxyoctanoic acid, but the highest concentration amount in claims 3 and 31 is only 25 ppm.

(2) Claims 33 recites “[t]he aqueous flume ... of claim 31, **comprising**” (emphasis added). The term “comprising” indicates that what follows after it is a listing of the flume components, not just a specific component that is further being specified. If the latter is the intention, “comprising” should be changed to “wherein.” Same type of problem is noted in claim 34.

Applicant is advised that should claim 31 be found allowable, claim 5 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei et al. (WO 99/51095) in view of Lokkesmoe et al. (WO 94/21122), FSTA abstracts 1999(10):C1223 and 2000(06):J1220 and Taylor.

Hei et al. disclose a sanitizing concentrate formulation that contains the following ingredients (see claims 17-25, see also p. 5, lines 30-32):

5-40 wt% C₂₋₄ carboxylic acid, for example acetic acid;
1-20 wt% C₈₋₁₂ aliphatic carboxylic acid, for example octanoic acid;
1-30 wt% hydrogen peroxide;
1-20 wt% C₂₋₄ peroxy-carboxylic acid, for example peracetic acid;
0.1-20 wt% aliphatic C₈₋₁₂ carboxylic acid, for example peroxyoctanoic acid; and
chelating agent.

The amount of chelating agent used is sufficient to "control or sequester hardness ions such as calcium and magnesium" to enhance activity and stability of peroxyacids (p. 11, first paragraph). Effective treatment and protection against microbial attacks are provided for *produce, fruits and vegetables*, as well as growing plants (p. 4, lines 3-16, in particular, lines 11-13; p. 16, Working

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Example 2). End use composition is made by diluting the concentrate formulation with major proportion of water to result in pH 2-8, 10-75 ppm C_{2-4} peroxydicarboxylic acid, for example peracetic acid, and 1-25 ppm C_{8-12} percarboxylic acid, for example peroxyoctanoic acid. See p. 4, lines 17-25. **Synergistic biocidal effect** is obtained with the disclosed combinations of two types of peroxyacids at pH<7 (p. 5, lines 10-16; p. 7, lines 14-20). Activity against a wide variety of microorganisms such as *E. coli*, *Salmonella javiana*, *Listeria monocytogenes*, yeast and molds are disclosed (p. 8, lines 19-22, pp. 16-18, Working Example 2 and Table 2) for combination of 50 ppm peracetic acid + peroctanoic acid (pp. 16-18, see in particular Table 2). Various method of achieving the final end use or equilibrium composition is taught – e.g., mixing C_{2-4} carboxylic acid + C_{8-12} aliphatic carboxylic acid + hydrogen peroxide + adjuvants (p. 11, lines 19-21) to obtain an equilibrium mixture. The level of active components in the concentrate is dependent upon the dilution factor and desired acidity in the use solution (p. 12, lines 11-12). Ratio of peracetic acid to peroctanoic acid ranges from 15:1 to 1:1, with there being at least 4 ppm peracetic acid and at least 1 ppm peroctanoic acid (see p. 5, lines 28-29; p. 9, lines 1-2).

Lokkesmoe et al. disclose a composition for preventing microbial growth in aqueous streams (p. 5, lines 3-6) that is made by combining 5-70 wt% hydrogen peroxide with 50-100 wt% carboxylic acid so that peroxyacids such as peracetic acid, peroctanoic acid or mixtures thereof is formed (claims 23-26). The end use concentration in the aqueous food delivery stream is 5-500 ppm hydrogen peroxide, 5-100 ppm peracetic acid, peroctanoic acid or mixture thereof

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(claims 27-29). 0.2-5 wt% Chelating agents are taught for stabilizing against premature oxidation (p. 9, lines 25-28; p. 10, lines 6-11).

FSTA abstracts 1999(10):C1223 and 2000(06):J1220 and Taylor et al. are cited to establish that peracetic acid or peroctanoic acid containing compositions would be expected to be effective against the type of microorganisms claimed by applicant. FSTA abstract 1999(10):C1223 discloses peracetic and peroctanoic acid to be effective against *Listeria monocytogenes*. FSTA abstract 2000(06):J1220 discloses 80 ppm Tsunami™ (i.e. peracetic acid) to be effective against *E. coli* O157:H7 and *Salmonella* in cantaloupes and honeydew melons. Taylor discloses mixture of hydrogen peroxide + peracetic acid to be effective against *E. coli* O157:H7 at both 20°C and 10°C (see Product code 13 on Tables 2 and 3).

The primary reference by Hei et al. does not explicitly disclose the specific amount of chelating agent, 0.1-2 wt%, as claimed in applicant's claims. However, guidance is provided to use an amount that is necessary to "control or sequester hardness ions such as calcium and magnesium" to enhance activity and stability of peroxyacids (p. 11, first paragraph). Lokkesmoe et al. provide the specific suggestion that this amount will be small, in the range of 0.2-5 wt% (see in Lokkesmoe et al., p. 9, lines 25-28; p. 10, lines 6-11).

The primary reference by Hei et al. also does not explicitly disclose in one single example, or in one single generic disclosure, an exactly matching range of component percentages and proportions, although Hei's percentages and proportions are sufficiently broad enough to encompass the claimed percentages. However, Hei et al. provide several critical

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teachings that would have motivated and led the skilled artisan to such specific claimed percentages. It is taught that end use, synergistic composition is made by diluting the concentrate formulation with major proportion of water to result in pH 2-8, 10-75 ppm C_{2-4} peroxy-carboxylic acid, for example peracetic acid, and 1-25 ppm C_{8-12} carboxylic acid, for example peroxyoctanoic acid. See p. 4, lines 17-25; see also claims 17-25; p. 5, lines 10-16; p. 7, lines 14-20. Therefore, given the known end use concentration of peracetic acid and peroctanoic acid that is useful for synergistic biocidal activity, which end use concentrations overlap with those of the instant claimed invention, one having ordinary skill in the art would have been motivated to arrive at such concentrations from correspondingly concentrated compositions prior to reaction and/or dilution. Various method of achieving the final end use or equilibrium composition is taught by Hei et al. – e.g., mixing C_{2-4} carboxylic acid + C_{8-12} aliphatic carboxylic acid + hydrogen peroxide + adjuvants to obtain an equilibrium mixture (p. 11, lines 19-21). The level of active components in the concentrate is dependent upon the dilution factor and desired acidity in the end use solution (p. 12, lines 11-12). Therefore, taken with the specifically disclosed concentrations of the concentrated formulation and the end use composition, and the fact the concentrated formulation itself can be made from a prior mixture hydrogen peroxide and carboxylic acids, one having ordinary skill in the art would have been motivated to capable of arriving at the various “concentrate” compositions,” “use composition,” and “equilibrium mixture resulting from ...” as claimed herein. In other words, given the end use concentrations of peracetic acid + peroctanoic acid that are known to be synergistic, taken with the disclosed

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concentrate formulation containing 5-40 wt% acetic acid, 1-20 wt% octanoic acid, 1-30 wt% hydrogen peroxide, 1-20 wt% peracetic acid, 0.1-20 wt% peroctanoic acid, and chelating agent, one having ordinary skill in the art would have been motivated and quite able to arrive at the various pre-concentrates (just hydrogen peroxide + carboxylic acids) and final diluted use composition and aqueous flume, as claimed (see below).

The primary reference by Hei et al. also does not explicitly disclose an aqueous flume for washing or transporting produce that contains the combination of components, as claimed in claims 5 and 31-34. However, Hei et al. clearly disclose treating produce per se, and Lokkesmoe et al. provide the suggestion that Hei's synergistically biocidal peracid-containing composition would be advantageous in aqueous flumes.

The primary reference by Hei et al. also does not explicitly disclose that the peracetic + peroctanoic acid containing composition would be effective for killing E. coli O157:H7. However, Hei et al. teach activity against E. coli in general, and secondary references by FSTA abstract 2000(06):J1220 and Taylor provide fair expectation that specific activity against E. coli O157:H7 would be obtained.

Applicant's argument that the claimed invention is a "carefully tailored" ranges of ingredients to provide "unexpected effect of killing three pathogenic bacteria" on the surface of a fruit or vegetable has been considered in this regard. Applicant points to specification Example 4, pages 24-26, but the evidence there and elsewhere is defective for several reasons. First, there is no disclosure as to what exactly was tested. Given the specificity of the claimed subject

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matter, the evidentiary disclosure must set forth the exact content of the tested composition with at least as much specificity as the claims so that it can be determined whether or not the a composition within the scope of the claimed subject matter showed nonobvious efficacy.

Second, given that Hei et al. teach that mixtures of peracetic acid + peroctanoic acid would be synergistic, applicant's comparison of the mixture with peracetic alone or peroctanoic alone is not a fair comparison. It is **expected** that the mixture would have higher efficacy. As a result, applicant's evidence does not establish nonobviousness, and furthermore, applicant's evidence is far short of being commensurate in scope with that of the claimed subject matter. In re Kulling, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); In re Lindner, 173 USPQ 356, 358 (CCPA 1972).

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the teachings of the cited references.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 7:30 AM to 4 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


JOHN PAK
PRIMARY EXAMINER
GROUP 1600